



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,188	02/25/2004	Teruaki Itoh	160-409 (AMK)	7412
23117 7590 11/10/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
WRIGHT, PATRICIA KATHRYN				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
11/10/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/785,188

Applicant(s)

ITO, TERUAKI

Examiner

P. Kathryn Wright

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 5 and 6 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/CDC)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed September 02, 2008 in which claim 5 was amended. The amendments have been thoroughly reviewed and entered. Any objection/rejection not repeated herein has been withdrawn by the Office. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 5-6 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 5-6 are again rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor (US Patent Pub. No. 2001/0010918) in view of Riggs (US Patent No. 5,814,276).

O'Connor teaches an inspection pretreatment system of bovine spongiform encephalopathy comprising a plurality of pretreatment devices. See the list of

equipment at beginning at para. [0063] and methodology beginning at paragraph [0084].

The plurality of pretreatment devices of O'Connor comprises:

- a first barcode label issuing unit for attaching a barcode label (i.e., bar-code label printer paragraphs [0048] and [0064]) on which predetermined information is recorded, the information includes information specifying the child specimen and for attaching the label onto the outer peripheral surface of the child specimen container (microtiter plate);

- a cell crushing device (stomacher homogenizer) for homogenizing cells of the parent specimen in the parent specimen container to which the barcode label has been attached by the first barcode label issuing unit;

- a dispenser unit (automated pipette) which dispenses a predetermined amount of the parent specimen homogenized by the cell crushing device so as not to include any solid and which dispenses the specimen as a child specimen in a child specimen container, see paragraph [0048];

- at least two refrigerators (deep freeze storage and refrigerated storage) capable of freezing the parent and child specimen containers (i.e., microtiter plate), see paragraphs [0072]-[0073] and [0161].

- a first addition unit (pipettes) which adds and immixes a reagent to the child specimen container to decompose protein;

- two incubation devices to heat the container containing the child specimen;

- a second addition unit (pipettes) which adds the reagent to the child specimen incubated in the first incubation device and which immixes the specimen until the specimen turns blue;

a centrifugal separation unit which subjects the child specimen obtained in the second addition unit to a centrifugal separation treatment to discard/dispose a supernatant liquid, see paragraph [0129];

a condensation unit which condenses the specimen and which holds the specimen in a still state (plate washer);

a dilution unit (pipette) which adds and immixes a predetermined amount of reagent D to the child specimen incubated in the second incubation device to dilute the specimen (see paragraph [0012]);

an inspection sample preparation device which dispenses and adsorbs a predetermined amount of the child specimen diluted in the dilution unit to a well of a micro-titer plate to prepare a sample for inspection for detection of pathogenic prion protein (see paragraph [0133]-[0137] for example); and

an inspection chamber (microtitration plate chemiluminescence reader).

Regarding claim 6, O'Connor teaches the plurality of pretreatment devices are controlled by a controller (microcomputer; paragraph [0069]).

O'Connor teaches all the claimed pretreatment devices, including a barcode assigned to the parent sample that includes predetermined information specifying the parent specimen (see para. [0048]). O'Connor also recognizes that subsequent containers should be assigned a barcode identical to the original sample to allow for full traceability throughout the system (see para. [0048]).

However, O'Connor does not explicitly recite the use of a specimen conveyor including at least one pair of belt conveyors, wherein the plurality of pretreatment devices are arranged along the conveyance path of the conveyor with the parent

Art Unit: 1797

specimen refrigerator and child specimen refrigerator located between a second barcode label issuing unit and the first addition unit. Nor does O'Connor explicitly recite a carry-in unit which carries in a parent specimen container containing a sampled parent specimen and which mounts the container on the specimen conveyor, a carry-out unit which carries the sample for inspection prepared in the inspection sample preparation device out to an inspection chamber, or an additional second barcode label issuing unit for attaching a barcode label onto the outer peripheral surface of the specimen container.

However, barcode label issuing units and sample conveyors having carry-in and carry out units are considered conventional in the automated analyzer art, see for example Riggs.

Riggs teaches a specimen conveyor system for moving the tubes in selectable routes through an automated blood sample processing system, The Riggs system also includes a carry-in unit (primary test tube loader 1A) for loading parent containers (primary test tubes), and a carry-out unit (sortation system 21) in which the child containers (secondary tubes) are made available for removal and subsequent processing. Furthermore, the Riggs system also includes a barcode label issuing unit (printer 17), label applying mechanism 18, and a spool 19 for attaching a barcode label having onto the outer peripheral surface of a specimen container (see col. 5, lines 37 et seq.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the inspection pretreatment system of O'Connor, the specimen conveyor system and barcode label issuing unit of Riggs. One

Art Unit: 1797

of ordinary skill would be motivated to do so since the use of barcode labels allows for full traceability throughout the system (see para. [0048]) of O'Connor.) Additionally, one of ordinary skill in the art at the time of the claimed invention would have been motivated to use a conveyor system to transport the tubes throughout the processing system since this would allow for continual processing/movement without the need of user interaction.

Regarding, the particular arrangement of the parent specimen refrigerator and child specimen refrigerator located between a second barcode label issuing unit and the first addition unit along the conveyance path of the conveyor, it would have been obvious to one of ordinary skill to arrange the plurality of pretreatment devices of O'Connor in order that optimizes the operational parameters of the system (time, throughput, etc). Further, it has been held that mere rearrangement of parts has no patentable significance unless an unexpected result is produced; see MPEP 2144.04 (C).

Response to Arguments

5. Applicant's arguments filed September 02, 2008 have been fully considered but they are not persuasive.

In response to the previous rejection of claims 5-6 under 35 U.S.C. 103(a) as being unpatentable over O'Connor (US Patent Pub. No. 2001/0010918) in view of Riggs (US Patent No. 5,814,276), Applicant argues that O'Connor lacks the parent specimen refrigerator for freezing the parent specimen and the child specimen refrigerator for freezing the container in which the child specimen is contained.

The Examiner respectfully disagrees with Applicant. First, the Office notes the instant claims do not specify the temperature at which the refrigerators are operated. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Secondly, O'Connor does teach at least two refrigerators (deep freeze storage and refrigerated storage) capable of freezing the parent and child specimen containers; see paragraphs [0072]-[0073]. Also, note that O'Connor teaches that the aliquots of specimen stored at -20 degrees C were stable over a seven day period. However, samples stored at 2-8 degrees, room temperature, and 37 degree C showed some deterioration (see for example [0161]) over the same time period. Thus, it is expected that the sample aliquots of O'Connor were stored at -20 degrees C in the refrigerators for increased stability.

Thus, for the reasons delineated above, claims 5-6 remain rejected over the cited prior art.

Conclusion

6. No claims are allowed.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797